AMERICAN UNIVERSITY
WASHINGTON, DC

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February 9, 2009

Committee on Human Services
Rep. Arlene Becker, Chairwoman
1301 East Sixth Avenue
Helena, Montana 59620

Dear Chairwoman and Members of the Committee:

It is my pleasure to submit these comments on the practice of prescriber profiling and the sale of physician-specific prescription data.

My name is Meredith Jacob and I am a pharmaceutical policy fellow at the Program on Information Justice and Intellectual Property (PIJIP) at American University Washington College of Law. I am here on behalf of the Prescription Project of Community Catalyst, as well as the National Legislative Association on Prescription Drug Prices. Additionally, PIJIP's associate director, Sean Flynn, serves as counsel to the Prescription Project of Community Catalyst and to the National Legislative Association on Prescription Drug Prices. These organizations strongly support the passage of legislation to regulate so called "data mining" by the pharmaceutical industry.

My comments include an overview of the practice of prescription data mining, a review of legislation passed in other states to regulate it, as well as an analysis of the recent decision of the United State Court of Appeals for the First Circuit upholding the New Hampshire data-mining restriction.

The Use and Abuse of Prescription Data Mining

Let me begin with a short description of prescription data mining and the problems it is causing to health systems.

The practice of prescription data mining dates back to the early 1990s, when prescription records went digital. That is the same period in which pharmacy benefit managers became widespread. These organizations sought to digitize prescription records so that claims could be processed through a quick online process. That change also created the possibility of quickly transferring the records to others.

Over the last decade or so, a multi-billion dollar "health information" industry has emerged to buy prescription records from pharmacies, PBMs and other intermediaries to compile massive databases on the prescribing habits of nearly every physician and other licensed

prescriber in the country. These databases are mined through sophisticated computer programs for information displaying individual prescribing trends and preferences.

The records are then used by pharmaceutical companies to guide incredibly sophisticated marketing efforts to doctors. Pharmaceutical companies use the records to determine which doctors are more susceptible to various kinds of sales messages, which are more prone to using new drugs, whether a doctor is "brand loyal" to a certain manufacturer, how doctors are responding to sales messages and to determine which doctors should be rewarded for their prescribing practices with high paying consultancies, advisory board positions, and scholarships to "educational" seminars.

One doctor emailed our program in January 2009 and said that:

> I have been told several times by different company reps that they will not support educational (even CME) programs because I do not order enough of their drug

Data mining radically increased the influence of marketers by allowing them to specifically observe and reward the most profitable prescribing practices while tailoring switching messages to those not using desired products.[1]

Access to prescribing data stoked a massive increase in spending and sales force size for individualized marketing. According to the First Circuit's examination of the record in the New Hampshire case, pharmaceuticals companies spend at least $4 billion a year on detailing expenses to doctors.

In the decade after IMS unveiled its flagship prescriber tracking program in 1993,[3] spending on detailing increased by nearly three hundred percent,[4] doubling the number of pharmaceutical sales representatives to over 100,000.[5]

There is now one pharmaceutical sales representative for every four to five office-based physicians in the nation. Because low prescribers often do not receive sales attention, it has been estimated that the effective ratio of sales representatives to targeted doctors is closer to one for every 2.5 doctors. The average primary care physician in 2004 interacted with a staggering 28 sales representatives each week.[8]

States are acting to regulate this use of prescription data for several core reasons:

First, prescriptions are part of medical records that document some of the most private and personal activities of people in society. Releasing these records into the public so that

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[1] *See* Elliott, *The Drug Pushers*, at 90-91; Liz Kowalczyk, *Drug Companies' Secret Reports*, BOSTON GLOBE, May 25, 2003, at A1.

[3] *IMS America Introduces Xponent, the First and Only True Prescriber Level Prescription Sales Database,* PR Newswire, Feb. 9, 1993, *available at Lexis.*

[4] *Trends.*

[5] Rayna Herman & Nick Dabruzzo, *2006 Access Report: The State of the Selling Environment*, Pharmaceutical Representative, July 2006, *available at* http://www.pharmrep.com/pharmrep/article/articleDetail.jsp?id=353927; Manchanda, *supra* note 43.

[8] Consumers Union; *Prescription for Change*, Mar. 2006, http://www.consumersunion.org/pdf/drugreps.pdf.

marketers can see what drugs people are taking and target marketing to their doctors based on that information invades a core privacy interest that states desire to protect.

Second, there is a large amount of data displaying that drug marketers in the U.S. are exerting undue influence over the prescribing practices in the health profession which is contributing to irrational prescribing practices that harm public health and unnecessarily raise the cost of health care;

Third, access to this data is corrupting the medical profession by allowing companies to use advisory board appointments, consultancies and gifts as direct payment for observed prescribing practices;

Finally, doctors themselves are pushing for this legislation in many states because access to individualized data is promoting the use of harassing and vexatious sales practices in which sales representatives attempt to hold doctors "accountable" for gifts and promises as they race toward the massive bonuses companies provide to reps based on their ability to shift prescribing practices.

As I describe further below, all of these purposes provide ample justification for state regulation in this area, regardless of any "free speech" arguments raised by the industry.

State Regulation of Data Mining

New Hampshire, in passing its Prescription Confidentiality Act,[2] was the first state in the nation to ban the trade in prescriber-identified prescription data for marketing purposes. Following the passage of the New Hampshire Act, Vermont[3] and Maine[4] passed laws that give physicians the right to opt-in or opt-out of sharing their prescription records (respectively).

First Circuit Upholds the New Hampshire Prescription Privacy Act.

As you may know, the first-in-the-nation prescription confidentiality law in New Hampshire was recently upheld under a constitutional challenge by the First Circuit Court of Appeals. All three judges on the First Circuit agreed that the law's core purpose of curbing irrational prescribing of higher priced drugs due to undue influence of marketers was sufficient in itself to justify any encroachment on the "commercial speech" rights of companies.

Two judges held that the law did not actually regulate any speech at all because prescription records sold a commodity on commercial markets are subject to traditional economic regulation free of any First Amendment Inquiry.

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[2] N.H. REV. STAT. ANN. §318:47 f (2006).
[3] V.T. STAT. ANN tit. 18 §4631 (2007).
[4] ME. REV. STAT. ANN. tit. 22 §1711-E (2007)

The third judge thought that the law did affect the commercial speech of detailers, by prohibiting them from informing their messages with the records, but held nevertheless that the law was adequately justified.[5]

The First Circuit Holds That Monitoring Prescription Data is Not Speech

The first area of inquiry for the Fist Circuit was whether or not the use of prescriber-identifiable data should be classified as speech. Here, the court found that the use of data prohibited by the New Hampshire Act constituted conduct, not speech. The Court reviewed other cases where language-related activities were regulated as conduct, rather than speech, and found that in the case at hand there was "scant societal value" to any informational component of the marketing uses of prescription data.

The Court went on to note that in this situation, information had become a commodity, and could be regulated as such. It recognized that the sale of prescription data did nothing to increase the free flow of information to doctors or patients, or to inform their decision-making in the marketplace. Finally, the Court reviewed precedent establishing that state actions that made speech unprofitable did not restrict speech, and observed that no provision of the New Hampshire Act foreclosed publication or open discussion of prescriber data.

Creating a Full Record

Although the only Circuit Court to address the issue unanimously held that states have every right to ban the sale of prescription records to serve public health concerns, the litigation in these cases indicates that legislatures must carefully justify their actions to survive court scrutiny.

If anything, the risks of litigation for the next state to act in this area have increased. The pharmaceutical industry is now looking for a circuit split so they can take this issue to the Supreme Court.

The most important thing the committee can do – other than carefully crafting legislation – is to create a full and persuasive record displaying the reasons for its action in this area. While I agree with the majority on the First Circuit that data mining legislation should not be subject to 1st Amendment scrutiny, the committee should assume that a court may differ on this opinion and that the law will have to meet what courts term "intermediate scrutiny."

This means that the law must directly serve a "substantial government interest," and be reasonably tailored to that interest.

There is a wealth of documentary evidence and expert testimony that can be brought to bear on these issues.

In summary: Allowing pharmaceutical companies to monitor the prescribing practices of physicians permits them to exert an undue influence on prescribing practices that heightens

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[5] IMS Health, Inc v. Ayotte, ___ F. 3d. ____, 2008 WL 4911262 (1st Cir. 2008).

irrational prescribing practices, raises health costs and, ultimately, harms patient health and welfare the protection of which is the most fundamental role of state governments.

Regulation of Datamining Prevents Undue Influence in Pharmaceutical Marketing

States have a paramount interest in combating undue influence of pharmaceutical marketers over prescribing decisions.

Nearly all direct to prescriber marketing is one sided because only the most expensive and profitable medicines, i.e. branded blockbuster drugs, are marketed through in-person detailing. Access to prescribing data aggravates the negative impacts of this one sided information market by permitting branded medicine marketers to observe and reward favored prescribing behavior.

Numerous studies and investigations have documented a significant, measurable, and increasing influence of direct to physician marketing at convincing doctors to adopt prescribing practices that are contrary to clinical guidelines and the weight of objective scientific evidence. An exhaustive data synthesis from over 500 published studies found conclusive evidence that pharmaceutical detailing guided by access to prescribing data "impact[s] the prescribing practices of residents and physicians in terms of prescribing cost, nonrational prescribing, awareness, preference and rapid prescribing of new drugs, and decreased prescribing of generic drugs."[6] The same study concluded that meetings with pharmaceutical representatives had a direct relationship to physician requests to add drugs to a formulary that had "little or no therapeutic advantage over existing formulary drugs."[7]

Access to prescriber data heightens undue influence by being used to target gifts and rewards. The most favored prescribers can receive hundreds of thousands of dollars in payments from drug companies for speaking engagements, research, and sitting on various advisory boards. We need to cut this chain so prescriptions are made based on evidence, not the lure of payments.

Regulation of Datamining Reduces Costs and Promotes Public Health

Undue influence by pharmaceutical marketing results in enormous costs to society that states have a compelling interest in restraining. These costs are measured not only in dollars, but in the degradation of public health that flows from increased prescribing of drugs that are less effective, and sometimes harmful, to patients.

Data mining fueled marketing increases cost without benefit to patients.

There are many examples of the successes of our super-charged pharmaceutical marketing system at shifting massive amounts of prescriptions toward newer, more expensive drugs that do not benefit patients.

One study, referenced in the New Hampshire legislative history, showed that using highly marketed branded medicines for high blood pressure instead of less expensive generic

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[6] Ashley Wazana, *Physicians and the Pharmaceutical Industry: Is a Gift Ever Just a Gift?*, 283 JAMA 373 (2000).
[7] *Id.*

therapies rated as more effective by national treatment guidelines increased U.S. health costs by $3 billion in 1996.[8]

Another study found that approximately forty percent of Pennsylvania Medicare patients on antihypertensive therapy were being prescribed medications at odds with clinical guidelines at a cost of $11.6 million per year in that state alone. Extrapolated to national levels, that same study found that marketing-driven non-rational prescribing costs the nation $1.2 billion for that class of drugs alone.

The aggregate financial costs to society of undue influence by pharmaceutical marketers is enormous. Nearly a third of the five fold increase in U.S. spending on drugs over the last decade can be attributed to pharmaceutical marketing efforts that shift doctors' prescribing from existing, effective, and lower cost (often generic) therapies to new and more expensive treatments. A significant amount of these irrational choices are influenced by pharmaceutical marketers knowing that an individual doctor is favoring the less expensive treatment and mounting a campaign to convince the doctor to switch treatments.

Increased prescription costs reduce access to medicines or force patients to cut spending on other necessities.

Increased cost of medications has a direct effect on patient health. In 2007, a review of medical literature found that up to 32% of seniors took less medicine than prescribed in a effort to reduce costs.[9] When datamining drives the prescription of more expensive alternatives, patients are needlessly forced to make purchasing decisions that can endanger their health.

Datamining accelerates unsupported, overly-broad adoption of the newest drugs.

One of the clear effects of data mining in marketing is that it demonstrably shifts prescribing patterns toward newer drugs. But newer there is a growing awareness that the rapid uptake of new drugs may threaten patient health in many areas where older therapies should remain the first line drugs of choice.[10] This is because newer drugs often have unknown side effects that is less true with drugs that have been on the market for significant periods of time.

This effect can be seen in the incredible marketing push and resultant prescription surge for Vioxx, Celebrex, and other COX 2 inhibitors, despite the lack of any conclusive medical evidence that they were more effective than older pain medications, or that the reduction in gastric side effects were significant for most patients.

And in the case of Vioxx, aggressive marketing using prescriber data helped facilitate the widespread adoption of a drug that was far more dangerous to patient health than existing alternatives or than the company's marketing messages admitted.

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[8] *See also* Michael Fischer and Jerry Avorn, *Economic Implications of Evidence-Based Prescribing for Hypertension: Could Better Care Cost Less*, 291 JAMA 1850, 1854 (2004).

[9] Becky A. Briesacher, et al., *Patients At-Risk for Cost-Related Medication Nonadherence: A Review of the Literature,* 22 J. GEN. INTERNAL MED. 864 (2007).

[10] *Drug Marketing Techniques May be Risking Patient Safety*, BRITISH MED. J. (press release) Dec. 2, 2008, *available at* http://www.eurekalert.org/pub_releases/2008-12/bmj-dmt120108.php.

Regulation of Datamining Maintains Standards in the Medical Profession.

Many physician organizations advocate an end to prescriber-identified data trading for marketing purposes because the practice threatens the ethical standards of the profession and jeopardizes their relations with patients.

There may be no greater affront to the ethical basis of the medical profession than permitting pharmaceutical companies to give pecuniary rewards to medical professionals based on their prescribing habits. Prescription data mining provides the key tool for pharmaceutical companies to literally pay prescribers with meals, gifts, vacations, high value / low work "consultancies," and board appointments for the use of their products.

Gift bans and reporting are one good policy tool. But it is difficult and perhaps impossible to ban all payments to doctors by pharmaceutical companies. Will we completely ban employing a doctor in a clinical trial or a consultant. Probably not. But we can ban these decisions from being made based on prescribing data so that the employment becomes a form of disguised kickback for profitable behavior.

Regulation of Datamining Protects Doctors Against Vexatious Sales Practices

Doctors are pushing many of the reforms in this area in part because a substantial number feel harassed by the increasing frequency and aggressiveness of detailing forces fueled by the use of prescribing data to track prescription writing and calculate sales bonuses.

There are a host of federal and state laws that combat harassing and frequent marketing calls on consumers by limiting marketers' access to identifying information. In the case of medicines, it is doctors who make the purchasing decisions for the ultimate consumers of the product, and therefore they receive the large majority of all marketing efforts.

In addition to being harassing by its sheer volume, access to prescriber detailing increases the prevalence of coercive marketing practices in individual sales calls. Sales representatives use this data in increasingly obnoxious ways to hold prescribers "accountable" for their marketing messages and gifts, including by telling prescribers that they are being monitored and that the free lunches and gifts will dwindle if they do not meet the marketers' expectations.

Regulation of Datamining Protects Patient Privacy.

There can be no doubt that patients have the strongest possible interest in not having their treatment histories subjected to surveillance and lobbying by pharmaceutical companies. But this interest cannot be protected by the removal of patient names alone.

Patient de-identification is not complete with the removal of names and addresses. The data can still be used to track an individual patient, identified with a unique numerical identifier that carries forward through time. With access to prescriber identities and "anonymized" patient data, a pharmaceutical company can observe a specific treatment event for a particular patient, like the switching of a prescription, and respond with an individualized marketing campaign at the prescriber to change that treatment. This insertion of the pharmaceutical company into the monitoring and influence of the patient's treatment is an

invasion of privacy of the most odious kind: one that directly affects the treatment course of the patient for the pecuniary interest of another through a breach of confidentiality that is nearly impossible to detect.

Deceptive Pharmaceutical Industry Arguments

The pharmaceutical industry misleadingly argues that this type of law limits their ability to target marketing to doctors based on specific prescribing habits, thus diluting the quality of the information they deliver. This is false, as individual physicians are free to tell marketers what type of drugs they prescribe if they desire more specific information from marketers.

The industry argues that laws protecting prescription confidentiality will limit use of prescribing data for research, or for efficiency-promoting health care utilization review. But these purposes are clearly exempted by existing datamining legislation.

Researchers testified in the New Hampshire litigation that they prefer to access Medicaid and Medicare treatment data for research purposes because it is more complete and private data is too expensive.

Data privacy measures have been in place in Europe and Canada for many years and we do not hear any evidence of problems in those jurisdictions. The companies can still collect identified data, they just cannot use it for marketing purposes and must contractually forbid any other recipient from using it for marketing purposes as well.

Conclusion

Thank you for this opportunity to testify. Please feel free to contact me with any questions, at 202-274-4157.

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Doctors, Legislators Resist Drugmakers' Prying Eyes

By Christopher Lee
Washington Post Staff Writer
Tuesday, May 22, 2007; A01

Seattle pediatrician Rupin Thakkar's first inkling that the pharmaceutical industry was peering over his shoulder and into his prescription pad came in a letter from a drug representative about the generic drops Thakkar prescribes to treat infectious pinkeye.

In the letter, the salesperson wrote that Thakkar was causing his patients to miss more days of school than they would if he put them on Vigamox, a more expensive brand-name medicine made by Alcon Laboratories.

"My initial thought was 'How does she know what I'm prescribing?' " Thakkar said. "It feels intrusive. . . . I just feel strongly that medical encounters need to be private."

He is not alone. Many doctors object to drugmakers' common practice of contracting with data-mining companies to track exactly which medicines physicians prescribe and in what quantities -- information marketers and salespeople use to fine-tune their efforts. The industry defends the practice as a way of better educating physicians about new drugs.

Now the issue is bubbling up in the political arena. Last year, New Hampshire became the first state to try to curtail the practice, but a federal district judge three weeks ago ruled the law unconstitutional.

This year, more than a dozen states have considered similar legislation, according to the National Conference of State Legislatures. They include Arizona, Illinois, Kansas, Maine, Massachusetts, New York, Nevada, Rhode Island, Texas, Vermont and Washington, although the results so far have been limited. Bills are stalled in some states, and in others, such as Maryland and West Virginia, they did not pass at the committee level.

The concerns are not merely about privacy. Proponents say using such detailed data for drug marketing serves mainly to influence physicians to prescribe more expensive medicines, not necessarily to provide the best treatment.

"We don't like the practice, and we want it to stop," said Jean Silver-Isenstadt, executive director of the National Physicians Alliance, a two-year-old group with 10,000 members, most of them young doctors in training. (Thakkar is on the group's board of directors.) "We think it's a contaminant to the doctor-patient relationship, and it's driving up costs."

The American Medical Association, a larger and far more established group, makes millions of dollars each year by helping data-mining companies link prescribing data to individual physicians. It does so by licensing access to the AMA Physician Masterfile, a database containing names, birth dates, educational background, specialties and addresses for more than 800,000 doctors.

After complaints from some members, the AMA last year began allowing doctors to "opt out" and shield their individual prescribing information from salespeople, although drug companies can still get it.

So far, 7,476 doctors have opted out, AMA officials said.

"That gives the physician the choice," said Jeremy A. Lazarus, a Denver psychiatrist and high-ranking AMA official.

Some critics, however, contend that the AMA's opt-out is not well publicized or tough enough, noting that doctors must renew it every three years.

The New Hampshire court's ruling has raised new doubts about how effective legislative efforts to curb the use of prescribing data will be, but the state attorney general has promised to appeal. And state Rep. Cindy Rosenwald (D), the law's chief sponsor, vowed not to give up the fight.

"In this case, commercial interests took precedence over the interests of the private citizens of New Hampshire," Rosenwald said. "This is like letting a drug rep into an exam room and having them eavesdrop on a private conversation between a physician and a patient."

The April 30 ruling by U.S. District Judge Paul Barbadoro, nominated to the federal bench in 1992 by President George H. W. Bush, called the state's pioneering law an unconstitutional restriction on commercial speech.

Since at least the early 1990s, drug companies have used the data to identify doctors who write the most prescriptions and go after them the way publishers court people who subscribe to lots of magazines. They zero in on physicians who prescribe a competitors' drug and target them with campaigns touting their own products. Salespeople chart the changes in a doctor's prescribing patterns to see whether their visits and offers of free meals and gifts are having the desired effect.

"It's a key weapon in determining how we want to tailor our sales pitch," said Shahram Ahari, a former drug detailer for Eli Lilly who is now a researcher at the University of California at San Francisco's School of Pharmacy. "The programs give them [doctors] a score of 1 to 10 based on how much they write. Once we have that, we know who our primary targets are. We focus our time on the big [prescription] writers -- the 10s, the 9s, and then less so on the 8s and 7s. . . . We're dealing with individual physicians who might give us the biggest dividend for our investment."

Ahari said he used the data to tout the virtues of Eli Lilly's antidepressant Prozac to doctors who favored the rival drug Effexor -- noting, for example, that its longer half-life meant that if patients missed a dose over a weekend, they would experience less severe agitation and other withdrawal symptoms that might prompt them to call their doctor. He did not mention the rival drug by name or disclose that he knew the physician's prescribing habits, he said.

Data-mining companies and the pharmaceutical industry argue that the practice has value far beyond the corporate bottom line. The information helps companies, federal health agencies and others educate physicians about drugs, track whether prescribing habits change in response to continuing medical education programs, and promote higher-quality care, they say. They stress that patient names are encrypted early in the process and cannot be accessed, even by the data-mining companies.

A drug company might use the database to help determine whether physicians prescribing a particular high-risk drug have undergone required training about the medicine, said Marjorie E. Powell, senior assistant general counsel for the Pharmaceutical Research and Manufacturers of America, a trade association.

"If you don't have that information, then you are in a very difficult situation," Powell said. "There is no way you can implement the risk-management plan that the FDA [Food and Drug Administration] is requiring you to implement in order to allow the drug to be on the market."

The prescribing data also let "the company do more targeted marketing, which lowers the total costs of

its marketing," she said.

Randolph Frankel, a vice president at IMS Health Inc., the Connecticut-based health-data-mining company that challenged the New Hampshire law, said the more a drug representative knows about a physician, the easier it is to provide information that meets the needs of the doctor's practice.

"We are about more information and more education, and not less," said Frankel, whose company had operating revenue of $1.75 billion in 2005, not all of it from sales to drugmakers. "The vast majority of physicians welcome these people as part of the overall educational process about drugs and their use. And any doctor in the country can close the door to these sales reps. It doesn't require legislation to do that."

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U.S. News & World Report
usnews.com

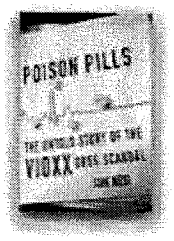
Wednesday, December 3, 2008

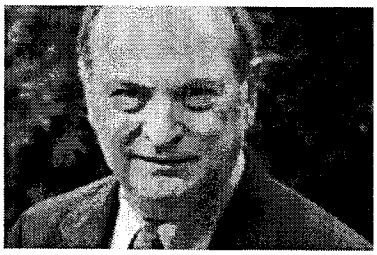
Former Pharma Pitchman: Beware of New Drugs

An insider speaks up on the Vioxx scandal—and reveals common tactics that dupe patients and doctors alike

By Sarah Baldauf
Posted September 18, 2008

Tom Nesi, author of the new book *Poison Pills: The Untold Story of the Vioxx Drug Scandal*, wants you to know what you're getting into when you pop a newly approved, heavily marketed prescription drug. A longtime director of public affairs at the pharmaceutical company Bristol-Myers Squibb, Nesi has more than 30 years' experience in medical communications and strategy. Now a writer and consultant, he comes off as no shill for the industry he once served.




Author Tom Nesi

His book focuses on the cautionary tale of Vioxx, the prescription painkiller that was pulled from the market after doctors belatedly realized that it caused heart, blood, and kidney problems—including some that were fatal. His broader objective, though, is to help consumers take advantage of good medicines while sidestepping the harm some can cause.

You say the most expensive drug you can take is a free sample. How is that?

They're very seductive—they're free. Merck distributed 17 million samples to 25,000 physicians and 375,000 patients. The problem is that if you've been doing fine on a 20-cent pill, you get the free sample for a month or two, then you have to go to the drugstore to fill the prescription and then it costs you $3 a pill.

You argue that in the context of pharmaceuticals, new is not always better. Why?

It's extremely important that people understand that, as extensively as a drug is tested before it's approved [by the Food and Drug Administration], it's still tested on a very small

population. It's also tested on a very select population. Drug companies don't go out to try to find the sickest patients to test their drugs on.

[With older drugs], not only is there more data but more usage experience. Doctors know how to use it—they become familiar with it. An example in the pain market: When some of these non-steroidal anti-inflammatories were released, like Motrin and Aleve, they were actually given at doses that were too high. As the years go by, [drugs] can actually become safer.

As a veteran drug marketer, you warn consumers to beware huge marketing campaigns for new drugs. In fact, you urge people to ask their doctors for proof that new drugs are superior to older ones before accepting a prescription for the newer medicine.

I would say the larger the marketing campaign, the more you should use caution. I would also say if there are good drugs in a category—in a type of illness that you suffer from—that have been out there for a while, there's no reason not to use those first.

How long should a drug be on the market before you try it?

I don't think it hurts to wait a few years. If you are in acute need, if you're just suffering horrible pain, you've tried everything under the sun and you need a new drug, well, that's entirely different than if you're satisfied. I would say, if you're satisfied with your current therapy, stay with it.

You caution women, in particular, to find out about a new drug's safety before taking it.

We know that some drugs interfere with reproduction. Any woman who is planning to get pregnant, or who potentially could get pregnant, should definitely discuss that with their doctor.

How often do doctors actually recommend their patients stop taking a prescription that works for them and start a newer drug instead? And how often do patients ask to change a medication they're doing well on?

It happens all the time. There are whole huge campaigns based on what they call switching behavior. A classic example that has just earned billions of dollars for no apparent reason: There was a drug I worked on, a very good drug called Prilosec, for treating heartburn, and

AstraZeneca, the company that had the patent, wanted to keep making money after Prilosec went off [patent], so they came up with a successor drug called Nexium, which is "the little purple pill." I remember working with a colleague [who, after looking at the preliminary data,] was just astounded and said, "Nexium doesn't work any better."

The Vioxx scandal is the main focus of your book. You contend that while the drug's maker, Merck, said it was collecting more data on Vioxx, thousands of people may have died. Is the lesson here to be skeptical when a pharmaceutical company says, "Not all the data are in yet" on a new drug?

Exactly. Some studies simply just get dropped. A lot of data just never gets published. There are ways of presenting data where not even the most sophisticated investigator could really tell what the data was really saying. One of the most disconcerting things, we know that there were more deaths among Alzheimer's patients who took Vioxx. The Alzheimer's trials for Vioxx were sort of published, but not with the complete data sets.

This book seems the antithesis, in some ways, of your life's work. Why did you write it?

My wife died about six years ago. She was very young, and she died of brain cancer. I went through experimental drugs, the talking to doctors—just about everything you can think of—and I found out that it was bogus. [Marketing medicines] was my life's career, and it forced me to really [re-]evaluate. I just didn't want to get out there anymore and tell people such-and-such a drug was a miracle compound when I knew that, (a) it wasn't, and (b) even if it was helping people, it was destroying their quality of life. So it caused me an entire career change—it just changed not just my career but my entire life. We're being duped.

Tags: FDA | marketing | prescription drugs | Merck | Vioxx

Public release date: 2-Dec-2008

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BMJ-British Medical Journal

Drug marketing techniques may be risking patient safety

Analysis: What can we learn from drug marketing efficiency?

With new drugs being reviewed by regulatory agencies and then released onto the market faster than ever before, patients' safety is being compromised, warns a study published on bmj.com today.

Dr David Kao from the University of Colorado Health Sciences Center, argues that while drug regulatory bodies are under pressure to make new drugs available more quickly, there are concerns that the deadlines for approving drugs have shifted the focus away from safety.

Kao reviews trends in drug approval times in the United States, and suggests how drug marketing techniques could be used to improve the way new drugs are monitored.

Previous research has shown that drugs approved in the US during the two months before the mandated deadline were more likely to be withdrawn for safety reasons or to carry a warning.

Today's marketing techniques are so sophisticated, says Kao, that once a drug has been approved the products can be released on websites within 90 minutes. He cites the example of Merck's new treatment (sitagliptin) for hyperglycaemia (high blood sugar levels)—within 14 days of approval 188 million patients or 73% of the insured US population had been targeted by the marketing campaign.

The danger with so many people trying a new drug very quickly, argues Kao, is that it can expose large numbers of patients to unknown risks. When Merck's anti-inflammatory drug Vioxx (rofecoxib) was withdrawn from the market for safety reasons it had been available for five years and 20 million patients had been exposed to it.

Regulatory agencies have been criticised for their dependence on drug companies for funding. The agencies often collect fees from drug companies so that they can hire staff to review the drugs more quickly. The European Agency for the Evaluation of Medicinal Products receives 75% of its funding in this way, 43% of the US Food and Drug Administration (FDA) budget is similarly derived, and the UK's Medicines and Healthcare Products Regulatory Agency is completely funded by drug companies.

The author believes that the systems for reporting adverse drug reactions must be improved and suggests using the very same effective drug marketing techniques to do this. For example, laws in the US already compel TV adverts to instruct patients experiencing negative side effects to report their symptoms to the FDA. This could be expanded to include campaigns dedicated to drug safety monitoring.

Kao concludes by saying that the only drug monitoring system that will minimise unknown risks must involve all the key players in healthcare, including doctors, regulatory bodies, drug companies and patients.

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HOW DRUG REPS KNOW WHICH DOCTORS TO TARGET.

Big (Brother) Pharma

by Jake Whitney
Only at **TNR Online** | Post date 08.29.06

For years Dr. Peter Klementowicz suspected that pharmaceutical sales representatives knew more about the prescriptions he was writing than they let on. Klementowicz, a cardiologist in Nashua, New Hampshire, would occasionally hear curious statements from drug reps, such as, "you're one of my targets." His suspicion peaked when a friend told him she overheard a group of reps at a local Panera Bread discussing ways to induce Klementowicz to prescribe their drugs. How did they know he wasn't *already* prescribing their drugs? It wasn't until last year, after Klementowicz's wife stumbled upon a two-year-old newspaper article, that he learned what more and more doctors are also just discovering: Drug companies know almost everything about which physicians prescribe which drugs and how often.

Klementowicz's case is unusual: His wife, Cindy Rosenwald, is a New Hampshire state representative. The revelation that drug reps knew about his prescribing habits prompted her bill--signed into law by Governor John Lynch this summer--that bans the sale for commercial use of prescription data throughout the state. Rosenwald's bill was the first of its kind to become law, but several other states are considering regulating what they increasingly see as an onerous practice. And it's not hard to see why.

For more than a decade, drug companies have been tracking physicians' prescription records. It helps their bottom line immensely by allowing their sales reps to hound and ply physicians who, they believe, are underprescribing their drugs. But the practice is only just starting to receive widespread attention. In fact, a 2004 survey sponsored by the American Medical Association (AMA) found that about 25 percent of doctors were still unaware of the practice. And they're not all happy about it, either. Some doctors see it as disruptive of their professional prerogatives. Others resent the violation of their privacy. But the real effects may be far worse than the physician outcry suggests. The real problem is financial: skyrocketing drug prices. Buying and selling prescription records is a lucrative business, and, perhaps as no other factor, it inflates the cost of drugs.

Pharmaceutical

· MASTHEAD

companies get prescription data in a few different ways. One is by buying the information from companies like IMS Health, which purchases and sorts records from pharmacies, hospitals, nursing homes, and insurance companies. This, itself, is a profitable business. Last year, IMS Health earned $1.75 billion in revenue--$848 million from "Sales Force Effectiveness" offerings. To help them understand pharmacies' records, drug companies must also access an AMA database called the "Physician Masterfile." This file is a detailed professional history of every physician in the United States, and it contains such unique identifiers as license and Drug Enforcement Agency numbers--which drug companies use to match doctors to prescription records, since not all records contain the doctor's name (patient names are always excluded).

Proponents of the practice--including the AMA, the pharmaceutical industry, and data-mining companies--say prescription data is crucial for research purposes. (In an e-mailed statement, Ken Johnson, senior vice president of PhRMA, the pharmaceutical lobby, said that the data has been used in a study by the Centers for Disease Control and Prevention to "reduce unnecessary prescribing" of antibiotics.) The real explanation is that it's quite good for the bottom line: It creates a cottage industry for middlemen like IMS Health and nets extra revenue at little cost for the AMA. (The organization wouldn't say how much it made from the lease of its Masterfile, but, according to its annual report, the group earned $44.5 million in 2005 from the sale of "Database Products.") But the real benefit is for drug companies, which collect the data because it allows them to target their marketing efforts on specific physicians with pinpoint accuracy (instead of only advertising in broad-penetration venues like medical journals and conferences).

A drug company's marketers can tell from the data not only how much of its drugs Dr. X is prescribing, but also whether Dr. X is a "high prescriber" in that drug class--which tells them if it should target Dr. X at all. Kathleen Slattery-Moschkau, a former rep who worked for Johnson & Johnson and Bristol-Myers Squibb, told me that the data was "sliced and diced" into various reports, such as the "Heavy Hitter List," which included the top physicians she should seek to "convert." "When I took Dr. Smith to dinner at that fancy restaurant," she says, "I could look at the following week's numbers to see if it had an impact. If not, I could try a different approach."

Jamie Reidy, a former Pfizer and Eli Lilly rep who skewered his erstwhile profession last year in *Hard Sell*, says prescription data "was our greatest tool in planning our approach to manipulating doctors." Reidy used prescriber reports to hone his sales tactics, which included befriending top physicians and wooing their office staffs. If the data showed that a particular doctor was a target physician, Reidy might treat the nursing staff to cocktails, where he'd make it clear that, if the doctor

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prescribed his drug over the competitors', "they'll be having regular happy hours." Slattery-Moschkau says that top prescribers are not only "targeted, wined, and dined," but also called upon repeatedly by different reps about the same drug. The idea is that each rep can bond with the doctor in a different way. "One might be a female who's kind of a looker, one might be a sports person who would bring [the doctor] to the game, one might be more analytical."

But tactics like these are expensive, and, while they may spike sales, the marketing expenditures also spike costs. The "extras" that reps give their top prescribers include expensive lunches and dinners, gift certificates, and fees for speaking at ostensibly educational events--all of this on top of the ubiquitous promotional trinkets that virtually all physicians receive, such as pens, notepads, mouse pads, tote bags, umbrellas, and stuffed animals. Faced with incentives like these, doctors often prescribe brand-name drugs where cheaper generics might have worked--and that is driving up insurance premiums and co-pays.

Skyrocketing prescription costs were a driving force behind Rosenwald's bill, and California, Arizona, Hawaii, and West Virginia have also considered restricting drug companies' access to the data. According to a spokesman for West Virginia's Office of the Pharmaceutical Advocate, although no legislation has yet been proposed, the state is "taking a look" at regulating the use of prescription data as a means for controlling drug costs. And, in California, negotiations over a bill like Rosenwald's have resulted in a unique program that will allow physicians to "opt out" of having their physician-specific data released to salespeople. But companies like IMS Health hope to discourage doctors from the opt-out with enticements of their own, such as educational newsletters, patient compliance reports, and data packages containing the prescribing information of physicians in their region and specialty.

The AMA has responded in two ways. First, it defends the practice as not only crucial to research, but also as a way for drug companies to actually *reduce* marketing costs. In a recent article for *Pharmaceutical Executive* magazine, the AMA's Robert Musacchio and IMS Health's Robert Hunkler argued that access to prescription data reduces drug costs by allowing "pharmaceutical promotion to be relevant and specific, making the whole process more cost-effective." While, on the surface, this argument seems to have merit, it fails to take into account the cost of the data itself on drug prices. And its implication that only certain physicians are targeted (while others are not) is false. Certainly--as reps like Reidy and Slattery-Moschkau explained--top prescribers are "targeted" more than lower-prescribing physicians. But this doesn't mean the latter are ignored by drug companies.

Second, the AMA has responded with its own "opt-out" program, known as the Prescribing Data Restriction Program (PDRP). Since July 1, the AMA has given physicians across the country the right to request that their physician-specific data be withheld from drug representatives. But critics of the AMA's opt-out, such as Rosenwald, say it is insufficient and fraught with holes--and, in light of the AMA's financial interest in the practice, it's just a self-policing measure intended to avoid more legislation. The authors of the *Pharmaceutical Executive* article even admit that avoiding more legislation is a goal: "If [the rules of the program] succeed, legislators will turn their attention elsewhere, and the

industry can hang onto one of its most valuable data sources."

And there are other worries about the PDRP. For one, prescription data will continue to be made available to drug companies, including their marketing departments--just not reps and their direct supervisors--so drug firms will be on the honor system to keep the data from salespeople. This could give rise, as Rosenwald points out, to executives "winking" at reps or giving other tacit signals to go after targeted physicians. Another problem is that compliance will be measured strictly by physician complaints. This means, conceivably, that companies could continue to provide reps with the data; they would just need to better hide it from doctors. Finally, and most significantly, the PDRP does not offer any potential reduction in drug costs. Whether or not pharmaceutical companies adhere to PDRP rules, they will still spend millions on the records and the Masterfile, which, as always, will be reflected in higher drug prices. Clearly the PDRP is not the answer.

While prescription data can be beneficial for research purposes--like locating appropriate physicians for clinical trials--patients do not benefit from drug companies' access to the data. As Slattery-Moschkau told me, "prescriber reports are a perfect example that the industry's direct-to-physician advertising has little or nothing to do with what is in the best interest of the patient. It's all about market share and grabbing market share from our competitors." Since the industry can't be trusted to police itself, only bills like Rosenwald's can make drug companies focus on research and development rather than conspiratorial Panera Bread bull sessions. And that's just fine by Peter Klementowicz.

JAKE WHITNEY is a freelance writer in New York.

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January 28, 2006

Drug Maker's Efforts to Compete in Lucrative Insulin Market Are Under Scrutiny

By GARDINER HARRIS and ROBERT PEAR

WASHINGTON — For years, Novo Nordisk, a Danish company and one of the earliest makers of insulin, has raced behind Eli Lilly to capture the lucrative insulin market in the United States.

When in 1996 Lilly started selling Humalog, a synthetic insulin with speedier blood-sugar control, Novo needed four more years to get approval to market a similar product.

When Lilly's huge sales force put Novo at a disadvantage, Novo fought back. The company hired hundreds of sales representatives. When Lilly struck a marketing deal with the Eckerd pharmacy chain, Novo responded with a partnership with Rite Aid.

But in its race, several former Novo sales representatives say, Novo may have crossed the line. Sales representatives paid at least one Rite Aid pharmacist to encourage switches from Lilly products or Novo's own lower-priced versions to higher-priced ones, according to documents and former and present company officials. Novo also paid doctors' assistants when prescriptions were switched, according to two former sales representatives.

Several former sales representatives said they were told by pharmacists and doctors' assistants that some patients first became aware of the switches when they picked up the new medicines at a pharmacy.

Officials from Novo and Rite Aid said that their activities were intended primarily to educate patients or improve care and that similar programs were common in the industry.

Karen A. Rugen, a spokeswoman for Rite Aid, said, "Our alliance with Novo Nordisk is standard industry practice." Ms. Rugen said, however, that Novo had paid one of Rite Aid's pharmacists directly, although she said that top Rite Aid executives had been unaware of the practice.

Susan Jackson, a spokeswoman for Novo Nordisk, said that the overall agreement between Novo Nordisk and Rite Aid "has benefited many people with diabetes."

Ms. Jackson would not address questions about payments made to doctors' assistants or a Rite Aid pharmacist, nor would she say how much Novo paid Rite Aid. But she said the partnership "is not unlike other agreements common in the industry that provide 'preferred status' for branded drugs."

But prosecutors are now investigating possible criminal violations. On Dec. 20, Novo said it had received a subpoena from the United States attorney for the Eastern District of New York for documents relating to its marketing practices.

The company said that it "believes that the investigation is limited to its insulin products." The subpoena indicated that "the documents are necessary for the investigation of potential criminal offenses," the company said.

Drug companies may pay for consulting or educational services, but federal anti-kickback statutes prohibit them from offering financial incentives to doctors or pharmacists to encourage or reward the prescribing of particular drugs, according to a 2003 guidance from the Department of Health and Human Services.

"In short, practices that may be common or longstanding in other businesses are not necessarily acceptable or lawful" in health care, the guidance states.

A Marketing Battle

The rivalry between Novo and Lilly illustrates the efforts companies will undertake to become No. 1 in a drug market, especially for chronic diseases like diabetes, which in the United States is a $3.3 billion market annually, according to IMS Health, a pharmaceutical information and consulting company.

From a business perspective, Novo's efforts were a great success. From December 2001 through November 2005, Novo's insulin sales rose 364 percent to $963 million while Lilly's insulin sales rose only 13 percent to $1.43 billion, according to figures provided by IMS Health.

The marketing programs were detailed in dozens of internal Novo and Rite Aid documents obtained by The New York Times. Three former Novo sales representatives described the programs. These people, some of whom spoke to The Times separately from one another, do not wish their names to be used because all still work in the industry and fear retribution. Parts of the programs were also confirmed by company officials and another sales representative who allowed their names to be used. The former sales representatives would not comment on whether they had filed whistle-blower lawsuits against Novo.

In its marketing battle with Lilly, Novo's sales representatives undertook a variety of efforts to persuade doctors to prescribe Novo's insulin products, one of which was known as the "anchor in the office" program.

Under this program, Novo sales representatives established contacts in some medical offices that served many diabetics, three former sales representatives said. The contacts were generally nurses or medical assistants responsible for monitoring diabetic patients. Officially, Novo paid these "anchors" to educate patients about Novo's products.

But two of the three former sales representatives who participated in the program said that Novo paid anchors as much as $25 for each prescription they helped switch to higher-priced insulin products.

Vikki Tolbert, a Novo district sales manager, said in an interview that "people are up in arms for no reason."

"Novo, like other companies, used to have a program to reimburse nurses and medical assistants," Ms. Tolbert said. "The purpose was not to switch patients, but to educate them and train them on insulin and insulin devices."

The formal program and the payments ended several years ago, Ms. Tolbert said, but some sales representatives still wanted to have trainers, or "anchors in the office."

"We would never tell a sales rep to pay anyone," Ms. Tolbert said. "That's crazy. But some reps do things of their own volition. They are out in the field by themselves every day. Managers are not with them. A pharmaceutical company cannot know what each individual sales rep is doing."

Deals Becoming Routine

A number of drug companies are running afoul of the anti-kickback law. In October, Serono Laboratories pleaded guilty to two counts of conspiracy and agreed to pay $704 million to settle criminal charges that it engaged in an elaborate kickback scheme to encourage sales of its AIDS drug, Serostim. In 2004, prosecutors accused Pfizer of paying doctors to prescribe its epilepsy drug Neurontin, and the company pleaded guilty to two criminal charges and paid $430 million.

State and federal prosecutors are investigating scores of other criminal and civil cases of marketing abuse, all of which are under seal. The possible health consequences for patients are rarely emphasized, however. For instance, physicians say aggressive marketing of insulin products can hurt patients.

Dr. David M. Nathan, director of the diabetes center at Massachusetts General Hospital and professor at Harvard Medical School, said that switching insulin prescriptions without providing thorough counseling to patients can be dangerous.

Newer, more expensive rapid-acting insulins begin working within five minutes. Older, cheaper insulins take 30 to 40 minutes to lower blood-sugar levels. Patients who are switched from older to newer insulins without their knowledge may wait too long to eat, Dr. Nathan said.

"If their blood-sugar levels drop too low, they can become confused, lose coordination, lose consciousness and have seizures," Dr. Nathan said. "This can result in accidents and even death."

Drug makers routinely provide financial incentives to managed-care firms for greater sales, but providing similar incentives to pharmacy chains can raise legal and ethical questions in part because pharmacists' advice to patients, like that of doctors', is supposed to be based on the best interests of patients, not pharmacists.

Still, deals between drug makers and pharmacy chains are now routine. As part of these deals, drug companies pay pharmacy chains for drug promotions that can range from simple refill reminders to efforts to switch patients to higher-priced drugs. If sales then rise, payments can increase, said Jeffrey Krinsk, a lawyer in San Diego who specializes in suing over the deals.

The companies say that these arrangements benefit patients, but some pharmacy regulators disagree, saying the partnerships may result in prescriptions being switched inappropriately, hurting patients.

David R. Work, executive director of the North Carolina Board of Pharmacy, said that his board had tried unsuccessfully to restrict such deals, one of the few boards to make such an effort. The practice of pharmacy, like that of medicine, is regulated by state boards.

"These switches have nothing to do with patient interest, they're all about money," Mr. Work said.

Novo's marketing campaigns also highlight the conflicting loyalties of many health care professionals. Doctors and their staff often consult for or receive gifts from drug makers, which may affect prescribing decisions. Pharmacists sometimes suggest one drug over another to patients for financial, not medical, reasons, pharmacy regulators say.

In April 2004, Novo Nordisk sent information to its field managers and sales representatives about marketing guidelines issued by the federal government and by a trade association for the pharmaceutical industry.

After reviewing the guidelines, a Novo sales representative sent an e-mail message to Ms. Tolbert, the Novo district manager, asking, "Are we allowed to do the anchors in the office then?" Ms. Tolbert replied, "As far as I know, and in discussing it with other managers, we are allowed to compensate for patient education."

In March 2004, Ms. Tolbert sent an e-mail message to sales representatives describing the purpose of Novo's marketing efforts.

"Our goal is 50 or more scripts per week for each territory," Ms. Tolbert wrote, according to a copy of the message provided to The Times. "If you are not achieving this goal, ask yourself if those doctors that you have such great relationships with are being fair to you. Hold them accountable for all of the time, samples, lunches, dinners, programs and past preceptorships that you have provided or paid for and get the business!! You can do it!!""

Preceptorships are consulting arrangements with doctors.

After Novo announced its partnership with Rite Aid in March 2002, Ms. Jackson, the Novo spokeswoman, was quoted in Diabetes Health magazine explaining that Rite Aid pharmacists "will actively intervene to introduce Novo Nordisk products."

Novo Nordisk produces a variety of insulin products, including preloaded syringes and synthetic versions. These products are often more convenient to use but are also more expensive than standard insulin. Since diabetes is a difficult disease to manage, convenience is important. But some doctors question whether the convenience of the new products is worth the premium prices.

One Pharmacist's Role

Lawrence M. Schultz, a Rite Aid pharmacist in Maryland, was paid by Novo to identify diabetics from databases in Rite Aid pharmacies, according to the three former Novo sales representatives.

Mr. Schultz or a pharmacy technician then contacted doctors to persuade them to switch their patients to higher-priced insulin products, according to the three former sales representatives. It is not known why doctors agreed to the changes, but the sales representatives say that they may have assumed the switch was required under the patient's insurance policy.

Two former sales representatives who contracted with Mr. Schultz and hired "anchors" say that Mr. Schultz, doctors' assistants and others told them that patients often only became aware that their prescriptions had been switched to a different insulin when they arrived at the pharmacy to pick up their medicines. The sales representatives said they knew of no patients who were directly harmed by these surprise switches.

Ms. Rugen of Rite Aid acknowledged that Rite Aid has a partnership with Novo but says that "no official at Rite Aid knew that Larry Schultz," the Rite Aid pharmacist, "was being paid by Novo Nordisk."

Mr. Schultz confirmed that he had "pushed Novo Nordisk" products. He refused to give details, but said: "Everything I did was done completely ethically. The one thing I would never do is put my job, or Rite Aid, in jeopardy."

Three Novo sales representatives who described Mr. Schultz's efforts on their behalf said they knew of no other Rite Aid pharmacist who received payments directly from Novo. But internal documents from Rite Aid provided to The Times show that Rite Aid executives urged pharmacists throughout the chain to dispense Novo products.

Rite Aid encouraged pharmacists to run computerized "drug utilization reports" to identify patients who could be switched, documents show.

Rite Aid had powerful financial incentives, documents show. In a letter to Rite Aid pharmacists in February 2005, top Rite Aid executives said, "Each Novo Nordisk product we dispense brings us 20 to 40 percent better profit margin." Moreover, they said, such sales add millions of dollars to Rite Aid's "bottom line."

Ms. Jackson, the Novo spokeswoman, said the company was "pursuing this matter with great urgency" and intended "to take remedial action in the event we find violations of our policies."

Carmen Catizone, executive director of the National Association of Boards of Pharmacy, said marketing deals between drug companies and pharmacy chains had often misled doctors and hurt patients. .

"We are opposed to plans where the financial interest of the manufacturer takes precedence over the patient's health," Mr. Catizone said. "To call a physician and say that we're changing a patient's medication and make it seem as if it's on behalf of the patient when it's actually part of

THIS STORY HAS BEEN FORMATTED FOR EASY PRINTING

Drug companies' secret reports outrage doctors

By Liz Kowalczyk, Globe Staff, 5/25/2003

Several months ago, a pharmaceutical company salesman told Dr. Mario Motta something that surprised him. The salesman, who had scheduled a 15-minute appointment with Motta, said he knew that the doctor had been prescribing a competitor's cardiac drugs -- and he wanted Motta to switch.

Motta had never discussed his personal prescribing habits with the salesman. "I said `How would you know that?' " Motta recalled. "I couldn't get it out of him, so I told him to leave."

Drug makers, in a level of detail unknown to many physicians, are spending millions of dollars to develop secret reports about individual doctors and their patients, according to consultants to the drug companies.

Most physicians know drug companies collect some information about which medications they prescribe. But they are often surprised by the depth of detail pharmaceutical makers now are buying about almost every US physician, mostly from large pharmacy chains. The details include whether doctors are switching specific patients from one drug to a competitor within days of it happening, and whether they treat many poor patients and may want free samples.

With many doctors now holding sales representatives to strict time limits when they visit, these "prescriber profiles" allow reps to tailor their pitches to individual physicians. They are an increasingly important tool in drug company marketing to doctors, which accounts for the largest portion, $16 billion, of the $19 billion that pharmaceutical companies spent on marketing in 2001, according to IMS Health, a Connecticut-based compmany that collects prescriber data.

"Average sales calls are shorter, and physicians are seeing fewer sales reps," said E.M. "Mick" Kolassa, a professor at the University of Mississippi and managing partner of Medical Marketing Economics, which provides consulting services to drug companies. "Because of this, the sales call has become a more precious commodity and companies need to make sure they're putting their resources in the right place."

But even though patient names are removed from the data, some doctors believe these secret reports -- which they say sales reps almost never discuss openly with them -- are an unwelcome intrusion into the doctor-patient relationship. Doctors worry that the reports allow sales reps to push expensive drugs more effectively in a health care system that already is struggling with soaring costs.

"The amount of information they have about us and our prescribing is staggering," said Dr. Mark Rohrer, an internist and geriatrician at St. Elizabeth's Medical Center in Boston. "The important thing is how it's used. If it's used by a rep to pressure me to provide a different drug than the one I'm prescribing, especially if there's a generic alternative, I don't think that's right."

Several drug makers, including Eli Lilly and Wyeth, and the Pharmaceutical Research and

Manufacturers of America, the industry trade group, would not comment on prescriber profiling.

Michael Barnes, vice president of business intelligence solutions at Dendrite International Inc., which provides prescription data to drug companies, said the data are used to promote safety.

For instance, the Food and Drug Administration buys Dendrite's prescribing data, which allows the agency to monitor cases in which large groups of patients are taking drugs that could have dangerous interactions, he said. The agency can then direct the company to educate doctors about the potential harm.

Prescriber profiles, albeit in a more rudimentary form, are a key element in the whistleblower lawsuit David Franklin filed against his former employer, Parke-Davis, now part of Pfizer, alleging illegal and off-label marketing of the company's top-selling epilepsy drug, Neurontin. Federal investigators are in settlement talks with Pfizer, which declines to discuss the case.

Franklin, who worked as a medical liaison for Parke-Davis from April to July 1996, said his supervisors would provide him with a doctor's prescribing record for the previous month before he went on a sales call.

A month later, they would send him the physician's new prescriptions, so he could see if the information he gave to the doctor led him to prescribe more Neurontin or other Parke-Davis drugs. Now sales reps can see within days if a doctor is responding to a pitch, he said.

If a doctor was prescribing a competitor's product, Franklin knew that his presentation should focus on undermining that product, he said.

Sales people also reviewed doctors' prescribing habits to determine who was loyal and should receive trips and gifts. The industry has since put in place voluntary guidelines discouraging lavish trips and gifts.

"The doctors it didn't work on didn't get the gifts anymore because it was throwing money away," he said. "Your physician would be stunned to find out what pharmaceutical reps know about them before they walk into the office. We were trained in how to use this information without letting the doctor know we had it. It was absolutely imperative that you never referred to the report."

Documents recently unsealed in Franklin's lawsuit in US District Court in Boston also show Parke-Davis conducted prescriber profiling to determine whether dinner meetings, lectures, and teleconferences persuaded physicians who attended to prescribe more Parke-Davis drugs. Sometimes it worked, according to the company's analyses, and sometimes it didn't.

Since the mid-1990s, drug companies have hired outside firms that purchase data on physicians from pharmacies and used the information in marketing. It's legal in the United States as long as patients are not identified. However, the Canadian province of British Columbia outlawed the practice in 1996. But in the last two years, the data have gotten more sophisticated. "What's really changed in the last year or two is the speed at which they can get it," Kolassa said.

Companies that buy data and sell it to drug makers are creating and advertising new products.

Verispan, based in Pennsylvania, promises on its website that a new product called Market Mover will deliver changes in doctor prescribing behavior four days after the close of the week. It's "the fastest available indicator of changes in individual prescribing behavior," the company says. The company now sends these prescriber "alerts" directly to the sales rep's laptop. Verispan executives would not discuss prescriber profiling.

Companies such as IMS Health purchased computer records or tap directly into the pharmacy computer and extract information on the 3 billion prescriptions US pharmacies fill annually, according to industry specialists. They combine this information with biographies on nearly 850,000 physicians compiled by the American Medical Association, which earns $30 million annually licensing detailed reports on physicians, including where they went to medical school, their fax numbers, and their specialties. About 20,000 doctors have opted to be removed from the list.

AMA past president Dr. Richard Corlin said the list serves an important safety function: It allows drug companies to immediately alert doctors to a problem with a drug or change in how a medication should be used. But after some of its own members began criticizing the AMA for providing the list for marketing purposes, the organization a year ago adopted guidelines for drug companies that license the data, saying they should not use it to pressure doctors to change drugs.

AMA officials said they would consider suspending a licensing agreement with any drug company that violated these guidelines, but that they haven't received any complaints from doctors to that effect.

Verispan, IMS, and other companies also now buy data not just on individual doctors, but on individual patients and the medications they're taking. Executives at CVS and Walgreens, as well as Dendrite's Barnes, said pharmacies remove patient names and identifying details from the data and assign each person a non-traceable number. But the data include information such as a patient's insurance provider, all the drugs a patient takes, and their doses. Pharmacies would not say how much they charge for the data.

Barnes said the patient data are crucial because they follow individual patients, so drug companies can see whether doctors are merely placing new patients on a competitor's drug or whether they're actually switching existing patients off of one drug and onto another -- a greater cause for alarm.

If a drug company, for example, finds doctors are switching patients off of its cholesterol-lowering drug after they don't respond to a 40-milligram dose, the company can direct its sales force to focus on telling doctors to increase the dose.

With doctor-specific data, drug companies could tell only if a doctor was writing more prescriptions for a particular medication, but nothing about who was getting the drugs. The patient-specific data allow drug companies to see changes in physician prescribing behavior eight months sooner, "which could save tens of millions of dollars for the company," Barnes said. Barnes said the more advanced data also are used to promote safety. The FDA buys Dendrite's prescribing data, for example; this allows the agency to monitor cases in which large groups of patients are taking drugs that could have dangerous interactions. The agency can then direct the company to educate doctors about the potential harm.

But even when it comes to pure marketing, Kolassa said he doesn't believe prescriber profiling is unethical. "It's done throughout business. Frito-Lay knows a lot more about you than Merck knows about individual physicians. They know whether you bought beer or Diet Coke with your corn chips. Besides, physicians can always tell sales reps to take a hike."

Liz Kowalczyk can be reached at kowalczyk@globe.com.

This story ran on page A1 of the Boston Globe on 5/25/2003.

ims

Date: February 6, 2009

Representative Arlene Becker
Chair of the Human Services Committee
State of Montana

Re: House Bill 394

Madam Chair and Members of the Committee,

IMS Health is a health information company that provides services to a diverse range of healthcare stakeholders in the public and private sectors in over 100 countries around the world. Our primary interest is in preserving the critical data assets and the *flow of anonymous* data which our nation will need to face the *serious* healthcare challenges ahead, and to continue efforts to improve quality and longevity for our population at an affordable price. We support efforts to protect the privacy of personal health information for patients and applaud your efforts to do so.

IMS also has few if any differences over the need to manage healthcare costs. Collectively, our quality of life depends upon it. We applaud efforts to manage utilization, chronic illnesses, and to increase the appropriate use of generics, which now represents over 70% of all prescribing in this country. We are aware of healthcare reform initiatives, and the complex set of alternatives and possible solutions under consideration at the state and federal levels of our government, such as HIT, universal healthcare, pay for performance and personal accountability.

In the context of that necessary debate, it is clear to us is that information will be absolutely necessary to enable these initiatives to succeed. Otherwise, it could be compared to performing surgery with blind folders. We will make trade-offs without knowledge of the risks and opportunities...and patients care will be compromised.

It is also of great importance to us that the principals that will guide healthcare reform going forward are protected and preserved today. That is why IMS is against data restriction laws which impede the free flow of important information that does not compromise the privacy of individual patients. These legislative proposals undermine the principal of transparency, which is a guiding principal in healthcare reform, repeatedly expressed by all health experts, agencies and thought-leaders of both political parties as well as AARP, SEIU, and a host of consumer advocacy organizations.

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Legislative efforts to restrict data to specific stakeholders in the healthcare system have been justified over time by a changing set of rationales, with little if any substance in facts. Initially, they were framed by their proponents in the context of patient and physician privacy to garner support and raise the level of fear around this issue when, in fact, no such risk exists. Today, we hear very little about privacy. Furthermore, two Federal Judges have said there is no privacy issue, supporting our contention that there was intentional exaggeration by some of the proponents of these bills in the first place.

When these arguments failed, it was suggested that these laws would reduce costs. This is a popular theme, but to date there is no information to support such conclusions; and there is significant information to the contrary that suggests marketplace practices already exist to manage cost, without the need for data restrictions that may compromise patient care:

- New Hampshire restricted these data for approximately 9 months in 2006-2007; with no impact on costs. If the availability of these data drives costs, how does one account for that?
- The dispensing of new brand medications (products with a market presence of 3 or less years) has declined from 5.7% of total prescriptions dispensed in 2003 to only 1.3% in 2008. At the same time, generic medication grew to represent approximately 70% of dispensed prescriptions in 2008. How would that lead one to conclude that these data were causing physicians to prescribe brand medications inappropriately?
- From 1999 to 2007, the use of prescriber-level data by pharmaceutical research company representatives increased by nearly 56% while the annual rate of prescription drug spend growth plummeted from over 15% to only 1.6%.
- Of particular importance, managed care practices are much more influential in determining what is dispensed. Based on clinical and cost considerations, using active formulary management, patient education, tiered co-pays, and offering patients lower-cost equivalents (generic or brand) when appropriate, managed care continues to lower costs. And they have done so in spite of price increases and a 31% increase in the overall number of prescriptions dispensed from 2003 to 2008.
- Managed Care practices are well established and effective in managing utilization and costs. Today, generic prescribing uptake and share have achieved a national average of 70% of dispensed prescriptions. Once again, how would one conclude that payers in the public or private sectors were being over-run by rampant or irrational prescribing practices?

These laws risk patient care by intentionally impeding the process that brings medical breakthroughs to patients on a timely basis.

- Slowing this process effectively delays treatment. That means patients who can benefit from newer medications may be harmed.
- This law affects all products regardless of patient benefit. Life-saving medications and documented advances will be impacted the same as marginal improvements. At a minimum to protect patients, the legislation should provide for an exception for proven medical breakthroughs (so-called "fast tracked drugs as determined by the FDA), cancer medications, life-saving therapies, safety warnings from the FDA, etc.? No such language exists in the bill.

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Proponents of these laws say the medical marketplace will disseminate all the information required for patient care when in fact recent studies published in the NEJM showed that patients are not routinely treated according to best practices. Further, the Institute of Medicine indicated that dissemination of proven practices throughout the healthcare system can take as long as 17 years!

In light of these problems and needs, IMS suggests that you are now considering legislation that would remove one of the tools that supports quality improvement and education.

Lastly, legislation restricting these anonymous data risks the health of a robust biotechnology industry.

As you will hear from the Montana Bioscience Alliance, these data allow a more efficient process for bringing medical innovation to patients. Without them marketing costs will increase and there will be a need for a relatively larger sales force. This information allows small companies to compete with large companies and fuels the emergent biotech companies that employ small sales forces to reach few physicians...who treat the small populations who may benefit ***(The proverbial needle in a haystack).***

Finally we object to the idea that Government should decide who has access to and use of information Government deciding to block the flow of information because it wants to control behavior represents a very dangerous precedent.

In conclusion, IMS believes that House Bill 394, if enacted, will ultimately hurt patients. We urge you to vote against its passage.

While this testimony is submitted without our being present, IMS would be pleased to respond to questions should they arise by the Members of this Committee.

Respectfully submitted,

Randolph Frankel

Randolph Frankel
Vice President, IMS Health

Eisai

Eisai Inc.

100 Tice Blvd., Woodcliff Lake, NJ 07677

February 8, 2009

The Honorable Arlene Becker
Chair, Human Services Committee
House of Representatives
State of Montana

Re: HB 394

Dear Madam Chair and Members of the Committee:

I am writing to you on behalf Eisai Inc. (Eisai). Eisai opposes HB 394, which imposes restrictions on the sale and use of prescriber-data, because it could hinder the physicians' access to the most recent information on prescription drugs, adversely impacting patient health and safety. Eisai supports physicians possessing all the necessary information to prescribe appropriate medications and to manage a patient's prescription therapy. Eisai must oppose HB 394, unless exceptions are made for chronic and seriously debilitating, or life-threatening diseases.

Eisai is proud of its human health care *(hhc)* mission that strives to bring new, life-saving and enhancing prescription drugs to patients in the most effective and efficient way possible. We discovered and provide Aricept®, the only therapy approved for mild, moderate and severe Alzheimer's disease, and we have an extensive oncology product line. Eisai is proud to have four (4) orphan disease drugs that enhance the lives of patients with severe and disabling diseases that have population demographics fewer than 200,000, such as myelodysplastic syndrome, a condition of oncologic origin. Eisai provides BANZEL™ for a population of approximately 300,000 that treats Lennox-Gastaut Syndrome, a severe epilepsy disorder that accounts for one (1) to four (4) percent of all childhood epilepsy cases.

Physician data is used to provide timely, efficient, and targeted dissemination of information to doctors and patients. Prescriber-data does not include patient-identifiable information, which is protected information under the Health Insurance Portability and Accountability Act (HIPAA). Eisai understands the privacy concerns regarding prescriber-data, and that is why Eisai supports the efforts of the American Medical Association's Prescription Data Restriction Program (PDRP), which strikes a balance between conflicted physicians by providing an opt-out from release of their prescription data, and others who can receive up-to-date safety information on the medicines they frequently prescribe.

Without the ability to use prescriber-data smaller and mid-size biotechnology companies may face increased barriers in trying to bring a drug to market because it will become more cumbersome and costly to educate physicians about their drugs. Many drugs made by smaller manufacturers are approved under the Orphan Drug Act, which defines an orphan disease as one that afflicts fewer than 200,000 individuals. Eisai manufactures drugs like ONTAK®, approved for cutaneous t-cell lymphoma (CTCL)—a rare, slowly progressive form of non-Hodgkins lymphoma and orphan disease—as well as the aforementioned Aricept®. As a mid-size company, not being able to target its communications with prescribers could make the cost to educate physicians about ONTAK®, Aricept® or other medicines prohibitive. Ultimately, this would put downward pressure on future research and development on orphan diseases and diseases with small demographic populations, such as myelodysplastic or Lennox-Gastaut syndromes.

Access to prescriber-data allows pharmaceutical companies to target necessary prescription information to specific physicians, which helps avoid clinicians in a broader audience from being overwhelmed by less-relevant information. For example, it would not typically make sense to target information or samples for cancer medicine to a cardiologist, neurologist, or gastroenterologist. With respect to sampling, legislation such as HB 394 that restricts information for the targeting of samples can also interfere with the value of these programs. Samples provide value to patients by allowing them to try prescription therapies before prescriptions are filled. Programs should not interfere with or make it hard for manufacturers to provide free samples.

Pharmaceutical manufacturers use prescriber-data to enhance patient safety as described above, but this information is also necessary to comply with various federal regulations and reporting requirements and quality initiatives.

- **Patient Medication Adherence** for chronic conditions**:** Use of prescriber-data can reinforce appropriate adherence to prescription medicinal therapies for chronic and seriously debilitating, or life-threatening conditions, which may help reduce costs in the long term.
- **"Risk Management Plan":** The Food and Drug Administration (FDA) may require a manufacturer to implement a 'risk management plan' for specific safety concerns. In these instances, Eisai may be required to monitor and ensure that prescribers are conveying essential safety information to patients. In these instances, prescriber-data restrictions may jeopardize patient safety for life-saving and enhancing drugs for diseases such as cancer, leukemia, Alzheimer's disease, and epilepsy.
- **Adverse health reporting:** Manufacturers, including Eisai, are required by federal law to report to the FDA any adverse event associated with an approved drug. Prescriber-data is useful in obtaining the necessary information regarding adverse events.
- **Drug recall:** In rare instances, prescriber-data is used when FDA regulations require that companies notify physicians about drug recalls.
- **Labeling changes:** Targeted communications are one of the ways in which companies like Eisai may notify physicians of important changes in safety information, including black box warnings, drug-drug interactions, and emerging adverse events.

For these reasons, Eisai urges the Committee to reject HB 394 and its restrictions on commercially available prescriber-data, allowing them to opt-out of these programs, or at a minimum, allow exemptions for programs in place for chronic and seriously debilitating, or life threatening conditions.

If you have any additional questions or concerns, please do not hesitate to contact me at (201) 746-2553 or at ray_frost@eisai.com.

Sincerely,

/s/

Ray Frost
Senior Director
Federal and State Affairs